Reviewed As To Form By
Legislative Service Commission

I_135_0476-3

135th General Assembly
Regular Session
2023-2024

Sub. H. B. No. 92

A BILL

To enact sections 3701.042 and 4729.71 of the Revised Code to establish the Prescription Drug Importation Program, to require the Department of Health to create an emergency stockpile and medical countermeasures program, to name this act the Save Ohio Safe Rx Act, and to make an appropriation.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF OHIO:

Section 1. That sections 3701.042 and 4729.71 of the Revised Code be enacted to read as follows:

Sec. 3701.042. (A) As used in this section:

(1) "Dangerous drug" has the same meaning as in section 4729.01 of the Revised Code.

(2) "Emergency stockpile" means a stock of biological products, drugs, medical devices, vaccines, and other supplies in such numbers, types, and amounts as appropriate to provide for and optimize the health security of this state, including that of children and other vulnerable populations, in the event

of a public health emergency.

(3) "Medical countermeasures" means medical supplies and medicines used to diagnose, prevent, or treat diseases related to chemical, biological, radiological, or nuclear threats, including antibodies, antimicrobial and antiviral drugs, blood products, diagnostic tests, personal protective equipment, and vaccines.

(B) Not later than ninety days after the effective date of this section, the department of health shall do all of the following:

(1) Create a program for the establishment of an emergency stockpile and the procurement of medical countermeasures;

(2) Issue invitations to negotiate or requests for proposals to conduct the program, including through the use of a turnkey solution;

(3) Contract with a third-party entity to conduct the program.

(C) In its response to an invitation to negotiate or request for proposal, a third-party entity shall include an assessment or description of all of the following:

(1) The planned stockpile and countermeasures inventory and methods for the following:

(a) Properly disposing spoiled or expired stockpile items and medical countermeasures;

(b) Renewing expired stockpile items and medical countermeasures;

(c) Selling unnecessary stockpile items and medical

countermeasures;

(d) Onboarding stockpile items and medical countermeasures into an inventory and quality management system;

(e) Relocating as needed stockpile items and medical countermeasures into the appropriate environment.

(2) The retrofit of a warehouse described in division (E) of this section to provide for the storage and management of an emergency stockpile and medical countermeasures as well as food and water and other supplies as follows:

(a) In the correct environment with appropriate security, temperature, and humidity controls;

(b) In compliance with industry licensing and regulatory standards, including the federal food and drug administration's current good manufacturing practice regulations as described in 21 C.F.R. Part 211;

(c) With warehouse space and surface lot area sufficient to access, maintain, inventory, and distribute such supplies.

(3) A staffing plan that does all of the following:

(a) Ensures warehouse staff have appropriate knowledge, skills, and training to maintain, organize, identify, and package medical countermeasures and other supplies;

(b) Demonstrates how staff will utilize the inventory and quality management system in day-to-day operations to support the program;

(c) Identifies the number of staff necessary to operate the warehouse at the direction of the department under the program.

(4) An inventory and quality management system that can do all of the following:

(a) Track and trace, in real-time, the state's emergency stockpile and medical countermeasures, including by number, type, location, and expiration date;

(b) Facilitate the regular testing, maintenance, and rotation of the emergency stockpile and medical countermeasures;

(c) Provide reporting to assist in the state's emergency response and recovery.

(5) The one-time and ongoing costs associated with retrofitting or renovations, utilities, inventory assessment and relocation, software, product maintenance or rotation, and staffing, as appropriate.

(D) To be qualified to contract with the department under this section, an entity shall meet all of the following requirements:

(1) Have submitted to the department, following an invitation to negotiate or request for proposals, a response that meets the requirements of division (C) of this section;

(2) Have at least three years of experience in establishing, procuring, maintaining, and managing emergency stockpiles and medical countermeasures for the federal government or any of its agencies;

(3) Manage at least one million square feet of combined warehousing for emergency stockpiles and medical countermeasures;

(4) Hold a license issued under Chapter 4729. of the Revised Code or by the licensing authority of another

jurisdiction authorizing the entity to obtain, possess, have custody and control of, and distribute dangerous drugs.

(E) The department shall review each submitted response to determine if the requirements described in divisions (C) and (D) of this section have been satisfied. The department shall contract only with an entity that satisfies those requirements.

In addition to the contract, the department and third-party entity shall enter into an agreement whereby the entity leases from the department space in the central warehouse that is owned by the department and located in this state. The third-party entity shall use the leased space to conduct the program, which may necessitate retrofitting the space as described in division (C)(2) of this section.

After entering into a contract with a third-party entity, the department shall notify in writing the governor, senate president, and speaker of the house of representatives.

(F) The third-party entity shall engage in all of the following activities under the contract:

(1) Obtaining all of the following for the program's emergency stockpile and medical countermeasures: antibodies, biological products, blood products, diagnostic tests, drugs, including antimicrobials and antivirals, medical devices, medical and other supplies, medicines, personal protective equipment, and vaccines, including those recommended by the federal food and drug administration;

(2) Managing the program's emergency stockpile and medical countermeasures, including by doing all of the following:

(a) Ensuring their storage at appropriate temperatures and humidity levels;

(b) Tracking supplies in real time;

(c) Monitoring expiration dates to ensure that the program's emergency stockpile items and medical countermeasures remain safe and effective;

(d) Securing the emergency stockpile and medical countermeasures in the warehouse.

(3) Replacing the program's emergency stockpile items and medical countermeasures that have expired with those that have not yet expired;

(4) Ensuring that the program's emergency stockpile and medical countermeasures remain ready for deployment in the event of a public health emergency;

(5) Complying with federal law, including the "Federal Food, Drug, and Cosmetic Act," 21 U.S.C. 301, et seq., and the "Pandemic and All-Hazards Preparedness Reauthorization Act of 2013," Pub. L. No. 113-5;

(6) Establishing a reporting system to notify the department during a public health emergency of the availability of specific emergency stockpile items and medical countermeasures and whether such items and countermeasures are near expiration or require maintenance.

Sec. 4729.71. (A)(1) In an effort to generate substantial cost savings for consumers of prescription drugs in this state, the state board of pharmacy shall develop a program for the importation of safe and effective prescription drugs from Canada, which shall be known as the prescription drug importation program.

(2) The board shall contract with a third-party entity to

perform on behalf of the board the duties described in divisions (B) to (D) of this section. To be qualified to contract with the board, a third-party entity must have prior experience with prescription drug importation.

(B) In developing the program, the third-party entity shall do all of the following:

(1) Identify wholesalers for the importation of prescription drugs;

(2) Identify prescription drug suppliers regulated under the laws of Canada or of one or more Canadian provinces or both;

(3) Identify the drugs expected to generate substantial cost savings for consumers in this state;

(4) Establish measures for importing only the following prescription drugs:

(a) Drugs that satisfy federal food and drug administration safety and effectiveness standards;

(b) Drugs that are expected to generate substantial cost savings for consumers in this state.

(5) Ensure that the program has the ability to comply with the transaction and tracing requirements of sections 581 and 582 of the "Federal Food, Drug, and Cosmetic Act," 21 U.S.C. 360eee and 360eee-1;

(6) Recommend a charge per prescription or another method of financing to ensure that the program is adequately funded in a manner that does not jeopardize significant cost savings to consumers, including adequate funding for the initial start-up costs of the program.

(C) Not later than four months after the effective date of this section, the third-party entity shall submit to the United States department of health and human services, in accordance with section 804 of the "Federal Food, Drug, and Cosmetic Act," 21 U.S.C. 384, a request for approval and certification of the program developed under division (B) of this section.

If the United States department of health and human services approves and certifies the program, not later than six months after receipt of the approval and certification, the third-party entity shall establish and administer the program.

(D)(1) In establishing and administering the program, all of the following apply:

(a) The third-party entity shall do all of the following:

(i) Comply with the requirements of 21 U.S.C. 384 as well as any conditions specified by the United States department of health and human services in its approval and certification of the program;

(ii) Enter into a contract with a wholesaler identified under division (B)(1) of this section;

(iii) Enter into contracts with one or more of the drug suppliers identified under division (B)(2) of this section;

(iv) Enter into a lease agreement with the department of health as described in division (D)(2) of this section;

(v) Enter into contracts with one or more entities located in this state for distribution of the imported prescription drugs;

(vi) Consult with health plan issuers, employers, pharmacies, pharmacists, health care providers, and consumers;

(vii) Develop a process by which health plan issuers, pharmacies, and health care providers may register to participate in the program;

(viii) Establish and periodically update the list of prescription drugs to be imported under the program and make the list available to the board;

(ix) Ensure that prescription drugs imported under the program are dispensed, sold, or distributed only in this state;

(x) Periodically provide to the board information identifying the prices of prescription drugs imported under the program and the locations where the prescription drugs are dispensed, distributed, or sold;

(xi) Establish a toll-free telephone line to answer questions and address the needs of consumers, employers, health plan issuers, pharmacies, health care providers, and others impacted by the program;

(xii) Conduct on an annual basis an audit of the program and share audit findings with the board;

(xiii) Make available to the board any information necessary for the board to prepare the report required by division (E)(2) of this section;

(xiv) Conduct any other activity required by the board in rules adopted under this section.

(b) The third-party entity shall negotiate with the board the fee to be paid to the entity for administering the program. The amount of the fee shall be either a markup of the drugs purchased or a percentage of the savings achieved under the program, as calculated by the board in consultation with the

department of administrative services.

(2) The third-party entity and department of health shall enter into an agreement whereby the entity leases from the department space in the central warehouse that is owned by the department and located in this state. The third-party entity shall use the leased space to store and aid in the distribution of imported prescription drugs under the program. The third-party entity may retrofit the space in an effort to ensure that the drugs are stored and distributed in accordance with the federal food and drug administration's current good manufacturing practice regulations as described in 21 C.F.R. Part 211.

(3) On the request of the board, acting in consultation with the department of administrative services, the third-party entity may, on behalf of state agencies, negotiate prices for and directly purchase any prescription drugs, including drugs such as insulin, epinephrine, and, as defined in section 3715.01 of the Revised Code, biological products and interchangeable biological products, from manufacturers whose drugs have been approved for use in the United States by the federal food and drug administration. Such negotiations and purchases shall be conducted according to the same terms and conditions as negotiations and purchases are conducted under the prescription drug importation program and the third-party entity shall be compensated for such negotiations and purchases in the same amount as described in division (D)(1)(b) of this section.

(E)(1) With respect to the information described in divisions (D)(1)(a)(viii) and (x) of this section, the board shall make the information available to the public on the internet web site maintained by the board. The board shall

periodically update the web site to reflect any changes in the information.

The board also shall engage in activities to generate public awareness of the program.

(2) Not later than eighteen months after the effective date of this section and every year thereafter, the board shall submit to the president of the senate, the speaker of the house of representatives, and the chairpersons of the standing committees of the house of representatives and senate that are primarily responsible for considering health issues a report regarding the administration of the program during the previous year. Each submitted report shall include all of the following:

(a) The prescription drugs included under the program;

(b) The number of pharmacies, health care providers, and health plan issuers participating in the program;

(c) The number of prescriptions for which drugs were dispensed through the program;

(d) The estimated cost savings to consumers, health plan issuers, employers, and this state over the previous year;

(e) The findings of audits conducted over the previous year;

(f) Any other information required by the board in rules adopted under this section.

(F) The board shall adopt rules as necessary to implement this section. The rules shall be adopted in accordance with Chapter 119. of the Revised Code.

Section 2. All items in this act are hereby appropriated

as designated out of any moneys in the state treasury to the credit of the designated fund. For all operating appropriations made in this act, those in the first column are for fiscal year 2024 and those in the second column are for fiscal year 2025. The operating appropriations made in this act are in addition to any other operating appropriations made for these fiscal years.

Section 3.

1	2	3	4	5
A		DOH DEPARTMENT OF HEALTH		
B	Dedicated Purpose Fund Group			
C	5CV3 440612	Emergency Stockpile	$0	$16,000,000
D	TOTAL DPF Dedicated Purpose Fund Group		$0	$16,000,000
E	TOTAL ALL BUDGET FUND GROUPS		$0	$16,000,000

EMERGENCY STOCKPILE

The foregoing appropriation item 440612, Emergency Stockpile, shall be used for the emergency stockpile and medical countermeasures program created in section 3701.042 of the Revised Code.

Section 4.

1	2	3	4	5

A		PRX STATE BOARD OF PHARMACY			
B	General Revenue Fund				
C	GRF	887403	Prescription Drug Importation Program	$0	$2,000,000
D	TOTAL GRF General Revenue Fund			$0	$2,000,000
E	TOTAL ALL BUDGET FUND GROUPS			$0	$2,000,000

PRESCRIPTION DRUG IMPORTATION PROGRAM

The foregoing appropriation item 887403, Prescription Drug Importation Program, shall be used for the Prescription Drug Importation Program, in accordance with section 4729.71 of the Revised Code.

Section 5. Within the limits set forth in this act, the Director of Budget and Management shall establish accounts indicating the source and amount of funds for each appropriation made in this act, and shall determine the manner in which appropriation accounts shall be maintained. Expenditures from operating appropriations contained in this act shall be accounted for as though made in, and are subject to all applicable provisions of, H.B. 33 of the 135th General Assembly.

Section 6. This act shall be known as the Save Ohio Safe Rx Act.